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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/760,100   | 01/16/2004  | Jonathan C. Heller   | 29191-707.501       | 7363             |
| 21971  | 7590        | 07/05/2006           | EXAMINER            |                  |
| WILSON SONSINI GOODRICH & ROSATI<br>650 PAGE MILL ROAD<br>PALO ALTO, CA 94304-1050 |             |                      | AGRAWAL, RITESH     |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1631                |                  |
| DATE MAILED: 07/05/2006  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/760,100

Applicant(s)

HELLER ET AL.

Examiner

Ritesh Agrawal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, and 63-75 drawn to a method of performing an assay in a mass spectrometer, classified in class 702, subclass 19.
- II. Claims 12-16, drawn to a method for performing analysis in a mass spectrometer, classified in class 702, subclass 19.
- III. Claims 17-24, drawn to a system for analyzing biological samples, classified in class 436, subclass 250.
- IV. Claims 25-62 drawn to a system for analyzing biological samples, classified in class 436, subclass 250.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, invention I relates to a method of comparison of case and control samples with some standard polypeptides whereas invention II relates to a method of comparison of case samples against control samples directly. Comparison of sets of samples directly against each other versus comparisons done through a third reference represent different methodologies of experimental design. As the two inventions represent gathering data

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based on different types of comparisons, a different search of comparison methods will be required.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the system of invention III represents a system specialized for the analysis of biological materials. The methodology of invention I can be used along with any spectrometer including those not used for biological analyses such as those used for analysis of inorganic compounds. As such, while a search of art against invention I will cover uses of a spectrometer, art against invention III will cover specialized modifications associated with biological measurement.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the system of invention IV represents a system specialized for the analysis of biological materials. The methodology of invention I can be used along with any spectrometer including those not used for biological analyses such as those used for analysis of inorganic compounds. As such, while a search of art against invention I will cover uses of a spectrometer, art

against invention IV will cover specialized modifications associated with biological measurement.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the system of invention III represents a system specialized for the analysis of biological materials. The methodology of invention II can be used along with any spectrometer including those not used for biological analyses such as those used for analysis of inorganic compounds. As such, while a search of art against invention II will cover uses of a spectrometer, art against invention III will cover specialized modifications associated with biological measurement.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the system of invention IV represents a system specialized for the analysis of biological materials. The methodology of invention II can be used along with any spectrometer including those not used for biological analyses such as those used for analysis of inorganic compounds. As such, while a search of art against invention II will cover uses of a

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spectrometer, art against invention IV will cover specialized modifications associated with biological measurement.

Inventions III and IV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, inventions III and IV make use of different methodologies for samples excitation and ionization where invention IV provides for a controllable mechanism. These differences will differently effect the ability of samples to be ionized and the extent to which ionization will occur. As such, a search for prior art against these different inventions will require the search of different areas of mass-spectrometry related research since different ionization states (for example partial versus full) are used for different types of experimental analyses.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

For group I (claims 1-11 and 63-75):

- A) a cancer disease state (claims 7, 70),
- B) a cardiovascular disease state (claims 7, 70),
- C) an infectious disease (claims 7, 70),

and D) pregnancy related disorders (claims 7, 70).

For group II (claims 12-16):

A) a cancer disease state (claim 16),

B) a cardiovascular disease state (claim 16),

C) an infectious disease (claim 16),

and D) pregnancy related disorders (claim 16).

For group III (claims 17-24):

A) a cancer disease state (claim 21),

B) a cardiovascular disease state (claim 21),

C) an infectious disease (claim 21),

and D) pregnancy related disorders (claim 21).

For group IV (claims 25-62):

A) a cancer disease state (claims 29, 35, 43, 55, and 62),

B) a cardiovascular disease state (claims 29, 35, 43, 55, and 62),

C) an infectious disease (claims 29, 35, 43, 55, and 62),

and D) pregnancy related disorders (claims 29, 35, 43, 55, and 62).

The species are independent or distinct because each disease is characterized by different types of mutations. As such, to consider all of the named diseases, one would need to consider differences in the way in which mass spectrometry is used to analyze mutations in nucleic acids, versus proteins and differences in the way in which mass spectrometry is used to analyze amino acid substitutions versus deletions versus protein modifications.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, for group I, claims 1 and 63 are generic. For group II, claim 12 is generic. For group III, claim 17 is generic. For group IV, claims 25, 31, 39, 46, and 56, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not



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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ritesh Agrawal *RA*

*John S. Brusca 26 June 2006*  
JOHN S. BRUSCA, PH.D  
PRIMARY EXAMINER